

to claims 1-21 are made. Applicants consider the claims allowable in their present form. The specification has been amended to reflect government support for research which lead to the present invention. The Examiner has withdrawn her objections/rejections of the presently claimed invention with the exception of her rejection of the present application under 35 U.S.C. §103.

The Examiner maintains her rejection that the present claims are unpatentable under 35 U.S.C. §103 as being obvious over a combination of de Boer, et al., U.S. patent no. 5,518,751 ("de Boer"), in view of Satter, et al., U.S. patent no. 5,770,247 ("Satter"). It is the Examiner's position that de Boer teaches that CLA in food compositions such as milk are useful in treating disorders such as diabetes. The Examiner points to column 1, lines 35-43 in support of that view. The Examiner recognizes that de Boer does not teach particularly that CLA is useful in a method of treating diabetes, the specific conjugated linoleic acids claimed or the amount of CLA of the present invention. The Examiner cites Satter for teaching a method of adding linoleic acid compounds into animal feed and cow's milk. Satter is also cited for teaching that linoleic acid compounds to be used may include *trans,cis*-9,11-octadecadienoic acid, *cis,cis*-9,11-octadiendioic acid or *trans,cis*-10,12-octadecadienoic acid.

From the teachings of the cited art the Examiner concludes that it would have been obvious to employ CLA in a method of treating diabetes and that it would have been obvious for one of ordinary skill in the art at the time the invention was made to incorporate about 1 mg to about 10,000mg/kg of body weight of the *trans,cis*-9,11-octadecadienoic acid, *cis,cis*-9,11-octadiendioic acid or *trans,cis*-10,12-octadecadienoic acid into a milk composition product useful in a method of treating diabetes. Applicants respectfully traverse the Examiner's rejection.

It is respectfully submitted that the Examiner has not made out a cogent case for obviousness. Indeed, it is respectfully submitted that the Examiner has seized on a brief,

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*ambiguous* statement in the background section of a U.S. patent to de Boer and combined that ambiguous disclosure with the teachings of Satter which are directed to increasing the CLA content of Cow's milk, to argue that the claimed invention is obvious. As will be argued in detail herein, the Examiner's argument is not cogent and represents a rejection based upon an impermissible *hindsight* reconstruction of the teachings of the two references in rendering the present invention obvious.

#### **de Boer Does Not Teach or Suggest the Use of CLA for Treating Diabetes**

Contrary to the Examiner's conclusions regarding the teachings of de Boer, de Boer *does not* disclose or suggest the use of CLA for the treatment of diabetes. In contrast, de Boer merely reiterates and summarizes the state of the art at the time of the filing of de Boer (September 8, 1994), which did not recognize the significance of conjugated linoleic acid in the treatment of diabetes. Contrary to what the Examiner has posited in making the rejection, the art clearly did not teach or suggest the use of CLA as a treatment modality for diabetes. Indeed, prior to the present application, it was not known that CLA, in contrast to  $\gamma$ -linolenic acid (GLA, commonly found in evening primrose oil, for example), could be used to treat diabetes.

The Examiner has cited no art, separate from the ambiguous disclosure in the background section of deBoer, which even arguably teaches or suggests the use of CLA for the treatment of diabetes. Indeed, the Examiner must contort the ambiguous disclosure of deBoer because the art actually failed to appreciate the present invention. Prior to the present application, CLA was not known as a treatment modality for diabetes, and indeed, the first report in the literature of the significance of CLA in the treatment of diabetes, was Applicants' own paper, *Biochem Biophys Res Commun*, March 27, 244(3) 678-682 (1998). The date of Applicants' paper is some four (4) years after the filing date of de Boer. A copy of the abstract of that paper is enclosed. Prior to the present application, CLA was known for its anti-carcinogenic and anti-atherogenic properties having cardiovascular implications. Also known in the art was that  $\alpha$ -linolenic acid and linoleic

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acid possesses properties which make it potentially useful in the treatment of cardiovascular disease (as indicated by de Boer). Thus, the disclosure in de Boer at column 1, lines 35-43, is completely consistent with the conventional understanding at the time of the filing of that reference and refers to the fact that it was known in the art to use linolenic acid in cardiovascular diseases and diabetes. It was, however, not known in the art, before the present invention that CLA could be used for the *treatment of diabetes or that it was a particularly effective treatment for diabetes.*

The ambiguous passage in de Boer, which the Examiner relies on for the teaching that CLA may be used to treat diabetes is found in the background of the invention section at column 1, lines 35-43 and is presented below:

"An important reason for enriching milk or milk powders with fats containing a high percentage of unsaturated fatty acids or strongly unsaturated fatty acids is to prevent or reduce cardiovascular diseases, atrophies, rheumatic disorders or diabetes. In particular, such products contain a high percentage of oleic acid, linoleic acid which may or may not be conjugated,  $\alpha$ -linolenic acid and unsaturated C<sub>20</sub> and C<sub>22</sub> fatty acids."

A fair reading of that ambiguous passage in the BACKGROUND OF THE INVENTION section of de Boer is that de Boer is merely reviewing the conventional understanding at the time of the filing of de Boer which failed to appreciate the particularly effective use CLA could have in treating diabetes. Thus, it may be accurately argued and concluded, that de Boer merely reiterates a broad discussion of the art which did not teach or suggest the use of CLA for the treatment of diabetes, but rather the use of one or more of the disclosed fatty acids to treat the indicated conditions. It is noted that the Examiner has not separately cited any reference which actually teaches or suggests the use of CLA for the treatment of diabetes and instead, relies on de Boer to make the rejection. Thus, de Boer does not teach the use of CLA for the treatment of diabetes, because the use of CLA to treat diabetes was first disclosed in the present application.

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**Satter Does Not Obviate the Deficiencies of de Boer**

Turning to the disclosure of Satter, this reference discloses a method of increasing the CLA content of cow's milk. Satter discloses that CLA has exhibited beneficial effects for humans and discloses a number of beneficial effects, *none of them diabetes*. Those effects are recited at column 1, lines 29-35 and include, reducing body fat and enhancing protein levels in humans and to prevent weight loss associated with immune stimulation. However, in Satter, there is no disclosure or even an oblique mention of diabetes or the use of CLA to treat diabetes. Satter is actually devoid of any teaching or suggestion which might be construed to enable one of ordinary skill to combine its teachings with those of de Boer in making a cogent rejection of the instant application.

It is respectfully submitted that a combination of de Boer and Satter does not disclose or suggest the present invention and that these references, in combination, only become relevant to the present invention *after one has read the instant application*. Thus, the Examiner's rejection is an example of hindsight reconstruction, a rejection which is impermissible under the law. See MPEP §706.02(j) and *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). This is especially true where, as here, the prior art, *in general*, does not disclose or suggest the claimed invention, and the Examiner relies for such teaching, on an ambiguous description of the prior art. As was stated in *In re Vaeck*, "the teaching or suggestion to make the claimed combination and the reasonable expectation of success must be found in the prior art and not based on applicant's disclosure." *In re Vaeck*, at 20 USPQ2d 1438, 1442. Without the reliance of any teaching of the use of CLA for the treatment of diabetes in the prior art other than the putative disclosure in de Boer, Applicants' respectfully submit that the Examiner is engaging in hindsight reconstruction of the invention in make the rejection.

In the present application, there is simply no cogent basis upon which to suggest that the prior art taught the use of CLA for the treatment of diabetes. While the disclosure in de Boer is

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unclear, the remaining art cited, Satter, is *inapposite* to the teaching. Yet, the Examiner, recognizing the deficiencies in the art, does not separately posit a prior art reference which teaches the use of CLA for the treatment of diabetes- that is because no independent basis exists. Applicants respectfully request the Examiner to cite whatever prior art may be available for the teaching that CLA is a particularly effective treatment for diabetes, independent of the ambiguous disclosure of de Boer.

It is respectfully submitted that the combination of cited references relied upon by the Examiner fails to render the present invention unpatentable. The first reference, de Boer, fails to teach CLA as a treatment modality for diabetes and instead, ambiguously describes the prior art in the background of the invention section, and the second reference, Satter, fails to even mention diabetes or its treatment. It is respectfully submitted that the combined teachings of the art do not make out a cogent obviousness rejection. Moreover, because the Examiner appears to have relied on Applicants' own specification to make the rejection, the obviousness rejection is actually impermissible. Applicants respectfully request the Examiner to withdraw the remaining rejections in the present application and allow this application to issue.

For the above reasons, Applicant respectfully asserts that the claims set forth in the present amendment are now in compliance with 35 U.S.C. Applicants respectfully submit that the present application is now in condition for allowance and such action is earnestly solicited.

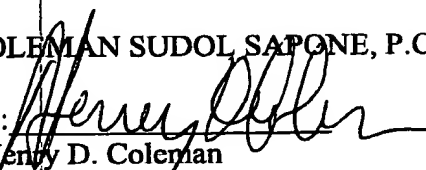
Applicant has neither cancelled nor added any claims. No fee is therefore due for the presentation of this amendment. A petition for an extension of time (one month) is enclosed as is a notice of appeal. The fee of \$215.00 should be charged to deposit account 04-0838. Applicants also submit herewith two Revocation of Power of Attorney and Appointment of Substitutue Counsel Forms, executed by the co-assignees of the present application. Small entity status is claimed for the present application.

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Please credit any overpayment or charge any additional fee due to Deposit Account No.  
04-0838.

Respectfully submitted,

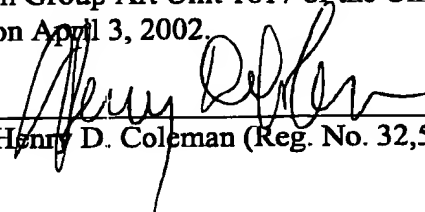
COLEMAN SUDOL SAPONE, P.C.

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Dated: April 3, 2002

**Certificate of Facsimile Transmission**

I hereby certify that this correspondence is being sent to Examiner San Ming Hui  
in Group Art Unit 1617 of the United States Patent and Trademark Office  
on April 3, 2002.

  
Henry D. Coleman (Reg. No. 32,559)

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**Appendix****In the Specification**

Cancel the first section header and first paragraph on page 1 and enter the following paragraph:

**-CROSS-REFERENCE TO RELATED APPLICATIONS AND SUPPORT**

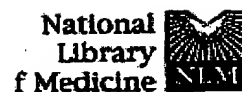
The present application claims the benefit of U.S. Provisional Patent Application Serial Number 60/069,567, filed on December 12, 1997, which is hereby incorporated by reference in its entirety. The invention of the present application was made using support under USDA Grant number 3299. Consequently, the government retains certain rights in the invention.--

**In the Claims**

No amendments have been made to the claims of the instant application. Previously filed claims 1-21 remain pending in the present application.

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- Biochem Biophys Res Commun 1998 Jun 29;247(3):911



### Dietary conjugated linoleic acid normalizes impaired glucose tolerance in the Zucker diabetic fatty fa/fa rat.

Houseknecht KL, Vanden Heuvel JP, Moya-Camarena SY, Portocarrero CP, Peck LW, Nickel KP, Belury MA.

Department of Animal Sciences, Purdue University, West Lafayette, Indiana 47907, USA.

Conjugated linoleic acid (CLA) is a naturally occurring fatty acid which has anti-carcinogenic and anti-atherogenic properties. CLA activates PPAR alpha in liver, and shares functional similarities to ligands of PPAR gamma, the thiazolidinediones, which are potent insulin sensitizers. We provide the first evidence that CLA is able to normalize impaired glucose tolerance and improve hyperinsulinemia in the pre-diabetic ZDF rat. Additionally, dietary CLA increased steady state levels of aP2 mRNA in adipose tissue of fatty ZDF rats compared to controls, consistent with activation of PPAR gamma. The insulin sensitizing effects of CLA are due, at least in part, to activation of PPAR gamma since increasing levels of CLA induced a dose-dependent transactivation of PPAR gamma in CV-1 cells cotransfected with PPAR gamma and PPRE X 3-luciferase reporter construct. CLA effects on glucose tolerance and glucose homeostasis indicate that dietary CLA may prove to be an important therapy for the prevention and treatment of NIDDM.

PMID: 9535724 [PubMed - indexed for MEDLINE]

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